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February 25, 2004

**TO: Examiner Nickol (TC1600)**

**GROUP: 1642**

**FAX NUMBER: 703-872-9306**

**ATTORNEY DOCKET NO.: PTQ-0040**

**SERIAL NO.: 10/059,920**

**FILED: January 29, 2002**

**NUMBER OF PAGES: 9**

**MESSAGE:** Attached please find Amendment Transmittal Letter, Reply to Restriction Requirement and Certificate of Transmission by Facsimile.

**Kathleen A. Tyrrell, Registration No. 38,350**

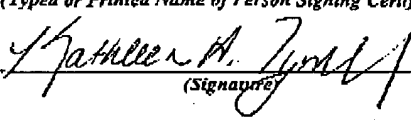
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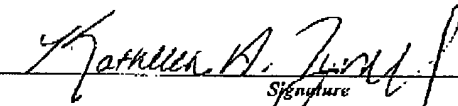
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<b>CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)</b> Applicant(s): Adams et al.		Docket No. <b>PTQ-0040</b>	
Serial No. <b>10/059,920</b>	Filing Date <b>January 29, 2002</b>	Examiner <b>Nickol, Gary B.</b>	Group Art Unit <b>1642</b>
Invention: <b>Methods for Diagnosing a Vascular Condition</b>			
<p>I hereby certify that this _____ <b>Reply to Restriction Requirement</b> _____  <small>(Identify type of correspondence)</small></p> <p>is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. <u>703-872-9306</u>)</p> <p>on <u>February 25, 2004</u>  <small>(Date)</small></p> <div style="text-align: right; margin-top: 100px;"> <p>_____  <b>Kathleen A. Tyrrell</b>  <small>(Typed or Printed Name of Person Signing Certificate)</small></p> <p>_____    <small>(Signature)</small> </p> </div>			
Note: Each paper must have its own certificate of mailing.			

<b>AMENDMENT TRANSMITTAL LETTER (Small Entity)</b>				Docket No. <b>PTQ-0040</b>							
Applicant(s): Adams et al.											
Serial No. <b>10/059,920</b>	Filing Date <b>January 29, 2002</b>	Examiner <b>Nickol, Gary B.</b>	Group Art Unit <b>1642</b>								
Invention: <b>Methods for Diagnosing a Vascular Condition</b>											
<u><b>TO THE COMMISSIONER FOR PATENTS:</b></u>											
Transmitted herewith is an amendment in the above-identified application.											
<input checked="" type="checkbox"/> Small Entity status of this application has been established under 37 CFR 1.27 by a verified statement previously submitted.											
<input type="checkbox"/> A verified statement to establish Small Entity status under 37 CFR 1.27 is enclosed.											
The fee has been calculated and is transmitted as shown below.											
<b>CLAIMS AS AMENDED</b>											
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE						
TOTAL CLAIMS	39 -	39 =	0 x	\$9.00	\$0.00						
INDEP. CLAIMS	4 -	4 =	0 x	\$40.00	\$0.00						
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00						
<b>TOTAL ADDITIONAL FEE FOR THIS AMENDMENT</b>					<b>\$0.00</b>						
<input checked="" type="checkbox"/> No additional fee is required for amendment.											
<input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of _____											
<input type="checkbox"/> A check in the amount of _____ to cover the filing fee is enclosed.											
<input checked="" type="checkbox"/> The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. <b>50-1619</b>											
<input checked="" type="checkbox"/> Any additional filing fees required under 37 C.F.R. 1.16.											
<input checked="" type="checkbox"/> Any patent application processing fees under 37 CFR 1.17.											
 Kathleen A. Tyrrell, Reg. No. 38,350			Dated: <b>February 25, 2004</b>								
Licata & Tyrrell P.C. 66 East Main Street Marlton, N.J. 08053 Tel: 856-810-1515 Fax: 856-810-1454			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the _____ for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</td> </tr> <tr> <td colspan="2" style="text-align: center;">_____ Signature of Person Mailing Correspondence</td> </tr> <tr> <td colspan="2" style="text-align: center;">_____ Typed or Printed Name of Person Mailing Correspondence</td> </tr> </table>			I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the _____ for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.		_____ Signature of Person Mailing Correspondence		_____ Typed or Printed Name of Person Mailing Correspondence	
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: PTQ-0040  
Inventors: Adams et al.  
Serial No.: 10/059,920  
Filing Date: January 29, 2002  
Examiner: Nickol, Gary B.  
Group Art Unit: 1642  
Title: Methods for Diagnosing a Vascular Condition

Certificate of Facsimile Transmission

I hereby certify that this document is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

On February 25, 2004

  
Kathleen A. Tyrrell, Registration No. 38350

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed January 26, 2004 setting a one (1) month statutory period for response. Please enter the following remarks into the record.

Remarks begin on page 2.

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Inventors: Adams et al.  
Serial No.: 10/059,920  
Filing Date: January 29, 2002  
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## REMARKS

Claims 51-89 are pending in the instant application. Claims 51-89 have been subjected to restriction as follows:

Group I, claims 51-63, as specifically drawn to a method for diagnosing hypoxia in an individual comprising measuring RTP/DRG-1 and PAI-1, classified in class 435, subclasses 6, 7.1;

Group II, claims 51-63, as specifically drawn to a method for diagnosing hypoxia in an individual comprising measuring RTP/DRG-1 and uPAR, classified in class 435, subclasses 6, 7.1;

Group III, claims 51-63, as specifically drawn to a method for diagnosing hypoxia in an individual comprising measuring PAI-1 and uPAR, classified in class 435, subclasses 6, 7.1;

Group IV, claims 51-63, as specifically drawn to a method for diagnosing hypoxia in an individual comprising measuring RTP/DRG-1, PAI-1 and uPAR, classified in class 435, subclasses 6, 7.1;

Group V, claims 64-71, as specifically drawn to a method for diagnosing progression of hypoxia in an individual comprising measuring RTP/DRG-1 and PAI-1, classified in class 435, subclasses 6, 7.1;

Group VI, claims 64-71, as specifically drawn to a method for diagnosing progression of hypoxia in an individual comprising

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measuring RTP/DRG-1 and uPAR, classified in class 435, subclasses 6, 7.1;

Group VII, claims 64-71, as specifically drawn to a method for diagnosing progression of hypoxia in an individual comprising measuring PAI-1 and uPAR, classified in class 435, subclasses 6, 7.1;

Group VIII, claims 64-71, as specifically drawn to a method for diagnosing progression of hypoxia in an individual comprising measuring RTP/DRG-1, PAI-1 and uPAR, classified in class 435, subclasses 6, 7.1;

Group IX, claims 72-80, as specifically drawn to a method for diagnosing preeclampsia in a pregnant woman comprising measuring RTP/DRG-1 and PAI-1, classified in class 424, subclass 9.1;

Group X, claims 72-80, as specifically drawn to a method for diagnosing preeclampsia in a pregnant woman comprising measuring RTP/DRG-1 and uPAR, classified in class 424, subclass 9.1;

Group XI, claims 72-80, as specifically drawn to a method for diagnosing preeclampsia in a pregnant woman comprising measuring PAI-1 and uPAR, classified in class 424, subclass 9.1;

Group XII, claims 72-80, as specifically drawn to a method for diagnosing preeclampsia in a pregnant woman comprising

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measuring RTP/DRG-1, PAI-1 and uPAR, classified in class 424, subclass 9.1;

Group XIII, claims 81-89, as specifically drawn to a method for assessing risk of metastasis comprising measuring RTP/DRG-1 and PAI-1, classified in class 436, subclass 64;

Group XIV, claims 81-89, as specifically drawn to a method for assessing risk of metastasis comprising measuring RTP/DRG-1 and uPAR, classified in class 436, subclass 64;

Group XV, claims 81-89, as specifically drawn to a method for assessing risk of metastasis comprising measuring PAI-1 and uPAR, classified in class 436, subclass 64; and

Group XVI, claims 81-89, as specifically drawn to a method for assessing risk of metastasis comprising measuring RTP/DRG-1, PAI-1 and uPAR, classified in class 436, subclass 64.

The Examiner suggests that Groups I-XVI are materially distinct methods which differ in objective, method steps, reagents and/or dosages and/or schedules used, response variables and criteria for success. Further, the Examiner suggests that the inventions of Groups I-XVI, inclusive of measuring at least two gene products, necessarily encompasses the analysis of four distinct and different combinations of gene products, each of which are unique and nonobvious.

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Applicants respectfully traverse this Restriction Requirement.

MPEP § 803 sets forth two criteria which must be met for a proper restriction requirement. The first is that the inventions be independent or distinct; the second is that there would be serious burden on the Examiner if the restriction is not required. Applicants do not believe that examination of the different combinations of gene products, at last for a specific diagnostic use, would place a serious burden on the Examiner. The Examiner states that the separate status in the art as shown by their different classification is indicative of this restriction being proper. It is respectfully pointed out, however, that contrary to the Examiner's suggestion, Groups I-IV, Group V-VIII, Groups IX-XII and Groups XIII-XVI are identified by the Examiner in this Restriction Requirement as being classified in the same class and subclass. Further, a search of these gene products will reveal any and all art references relating to any of their various utilities. Thus, including all Groups in the prosecution of this application should not place any undue or serious burden on the Examiner.

Accordingly, since this Restriction Requirement does not meet both criteria to be proper, reconsideration of this

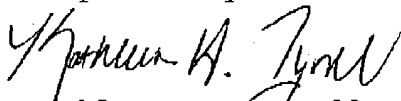


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Restriction Requirement and searching and examination of pending claims 51-89 of the instant application are respectfully requested.

However, in an earnest effort to be completely responsive, Applicants elect to prosecute Group XIV, claims 81-89, drawn to a method of assessing risk of metastasis comprising measuring RTP/DRG1 and uPAR, with traverse.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: February 25, 2004

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